

N.K.O.B.®

(New Kim on the Block)



Injectable Polymer Construct for Tissue Engineering Articular Cartilage

Mark Shreve
Jessica Yankovich
Mira Kim

Submitted to:
Dr. Miguel Bagajewicz

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1. Executive Summary

N.K.O.B.® Corporation's express goal is to develop a more viable solution to the increasing need for articular cartilage repair. There are thousands each year that receive treatment for articular cartilage trauma or degeneration, and due to an aging population this number is expected to grow. Total success is not realizable with current treatments. Thus, N.K.O.B.® will develop and market an injectable polymer scaffold, with encapsulated autologous cells and growth factors which may be injected into an articular cartilage defect, resulting in regeneration of tissue. This treatment will be wholly less invasive than any treatment on the market as of today, and will decrease the need for follow-ups while increasing the success rate of articular cartilage regeneration.

Through an evaluation of the current market and the FDA approval process, N.K.O.B.® has estimated that it will take an expected value of \$108,000,000 to pass the FDA approval process. The process may take approximately 16 years to complete on average, however, this amount of time may fluctuate due to any successes or failures throughout the process. The most financially burdensome portion of the process involves the clinical human trials, which are estimated to cost about \$100,000,000. Through a risk simulation, N.K.O.B.® has chosen to utilize 1 PhD and 10 Laboratory Technicians for the pre-FDA testing phase. This reduces the risk that N.K.O.B.® will take due to a better chance of approval in the FDA approval process.

The Fixed Capital Investment required by N.K.O.B.® is estimated to be about \$3,000,000. This cost includes construction of a facility and purchase of all required equipment. This brings the total investment for the project to be \$111,000,000, which includes the fixed capital investment, FDA approval costs, and clinical costs.

N.K.O.B.® has chose to determine the price of the product through existing demand and competitor's prices. Based on this, N.K.O.B.® will charge a fee of about \$11,000 for the cost of culturing, preparation of the polymer, and shipping. This will allow N.K.O.B.® to break even in three years time. After 10 years the expected cash flow will total \$112,000,000 for that year.